UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION **THIS DOCUMENT RELATES TO:** *Wisconsin, et al v. Indivior Inc. et al.*	**MDL No. 2445** **Master File No. 2:13-MD-2445-MSG** Case No. 2:16-cv-5073-MSG
STATE OF WISCONSIN **By Attorney General Brad D. Schimel, *et al.*,** **Plaintiffs,** **v.** **INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC.; *et al.*,** **Defendants.**	**Civ. A. No.16-cv-5073**

MEMORANDUM OF LAW IN SUPPORT OF MONOSOL RX, LLC'S MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

Thomas M. Barba (Pa. Bar #30057)
James F. Hibey
Kenneth P. Ewing
Andrew J. Lee
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, N.W.
Washington, D.C. 20036
Tel.: (202) 429-3000
Fax: (202) 429-3902
jhibey@steptoe.com
kewing@steptoe.com
alee@steptoe.com
Attorneys for MonoSol Rx, LLC

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATE STATUTES

INTRODUCTION

Over three years after private plaintiffs initiated class actions relating to the introduction of Suboxone® film, forty-one states and the District of Columbia now seek to drag MonoSol Rx, LLC ("MonoSol")—the inventor and leading manufacturer of pharmaceutical film—into a related case based on a surprising theory fundamentally at odds with the antitrust and related laws under which they sue. Having invented pharmaceutical film as a new way to deliver medicines, MonoSol partnered with Reckitt Benckiser Health (UK), Ltd. ("RBH") to develop a new and cheaper film form of RBH's opioid addiction medicine Suboxone®. The Plaintiff States attack MonoSol's participation in this new product introduction, on the theory that supplying technology and manufacturing services that enable a branded pharmaceutical maker to develop and market a new form of its drug that is not "AB-rated" under federal drug regulations, so as to permit automatic generic substitution under state laws, is a conspiracy to violate the antitrust laws. Yet, it is well settled that bringing a new product to market *increases* competition and *expands* consumer choice. *See, e.g.*, *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 696-98 (E.D. Pa. 2004). Neither the Sherman Act nor the state antitrust and consumer protection statutes that Plaintiffs cite condemn any of MonoSol's alleged conduct in marketing its technology or in developing and manufacturing the new drug. Because the State Plaintiffs' strikingly ***anti-competition*** theory is not the law, the Court should dismiss all claims against MonoSol in the First Amended Complaint ("FAC").

None of the Plaintiffs' allegations stands up to scrutiny. MonoSol's alleged *suggestion* to "Reckitt"[1] to withdraw the Suboxone tablet from the market could not itself plausibly have reduced competition in the alleged relevant market. And Plaintiffs have alleged no facts

[1] References herein to RBH, Indivior, Inc. and Indivior PLC collectively as "Reckitt" are solely for consistency with the allegations in the FAC. Plaintiffs fail to specify properly the allegedly wrongful conduct of each of RBH, Indivior, Inc. and Indivior PLC.

showing that MonoSol had any control over Reckitt's marketing of Reckitt's brand-name Suboxone tablet. Moreover, even assuming actual withdrawal of the brand-name tablet before entry of the generic tablet could, in theory, have injured competition, the FAC is clear that the brand-name Suboxone tablet remained available until after the entry of the generic Suboxone tablets. Similarly, MonoSol's alleged participation in unspecified exploratory meetings about a potential citizen petition fails to allege anti-competitive conduct by MonoSol. The petition was Reckitt's and MonoSol did not sign on; there are no allegations that MonoSol drafted or even reviewed a draft of the petition; and, in any event, "petition[ing] the Government for a redress of grievances" is protected under the First Amendment. U.S. Const. amend. I. Finally, allegedly pricing film below the tablet could not have been anticompetitive unless the price was below cost; yet, Plaintiffs allege that the film was profitable. Lower prices because of a lower cost structure represent nothing other than competition on the merits that benefits customers. *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223 (1993).

In addition to Plaintiffs' failure to allege any exclusionary conduct by MonoSol, the Court has at least five other independent grounds for dismissal. First and foremost, Plaintiffs do not and cannot plausibly allege an antitrust conspiracy between MonoSol and Reckitt. All they allege is that MonoSol and Reckitt are business partners, not competitors and certainly not co-conspirators. Their economic interests are aligned in seeking profits from sales of a new patented product, which courts recognize precludes antitrust conspiracy. Second, Plaintiffs fail to allege facts showing that MonoSol's conduct as co-developer and manufacturer of a cheaper alternative to the brand-name Suboxone tablet injured competition in any way. Third, the allegations of relevant market and specific intent to monopolize are fatally deficient. Fourth, Plaintiffs' claims are time-barred because all of the allegedly anti-competitive conduct by

MonoSol occurred outside of the four-year statute of limitations. Fifth, the FAC fails to state a claim under the various state statutes because the state-law claims parallel the insufficient Sherman Act claims, are not properly pled with particularity, or are time barred.

In sum, the FAC plausibly alleges only that MonoSol provided technology and manufacturing services that enabled Reckitt to introduce a new Suboxone treatment to compete with generic Suboxone tablets. This Court has held that merely introducing Suboxone film was not by itself anticompetitive. Allowing this case to proceed against MonoSol would encourage baseless claims of Sherman Act violations against every supplier of inputs, services or know-how used to develop a new, patented version of any product. The case should be dismissed.

BACKGROUND

A. Relevant Aspects of the FDA Regulatory Framework

The pharmaceutical industry is heavily regulated. The Food and Drug Administration ("FDA") must approve each new medicine before it goes to market. 21 U.S.C. § 355(a). To obtain FDA approval for a new, brand-name medicine, pharmaceutical companies submit a New Drug Application ("NDA") with information about the drug's therapeutic indications, effectiveness, and safety, among other items. *Id.* § 355(b); FAC ¶ 26. During a long review process, the new drug developer conducts studies, holds meetings with the FDA and submits evidence to address the FDA's concerns. *See, e.g.*, *Apotex*, 383 F. Supp. 2d at 690.

The FDA follows an abbreviated process for approval of generic versions of brand-name drugs if the manufacturer shows that the generic drug has the same therapeutic effect as the approved drug. FAC ¶ 28. The FDA classifies generic products as *therapeutically equivalent* to an approved drug if, among other things, the applicant establishes that the two are (1) *pharmaceutical equivalents*, *i.e.*, that they contain identical amounts of the same active drug ingredient *in the same dosage form* and same route of administration, and are (2) *bioequivalent*.

Id. ¶ 29. If a generic manufacturer establishes such therapeutic equivalence, then the FDA may give the generic drug an "AB-rating." *Id.* ¶ 30. Some states permit, and some require, pharmacists, to substitute an AB-rated generic version of a drug for a brand-name drug prescribed by a physician. *Id.* ¶ 32. Some states allow pharmacists to substitute even a non-AB-rated generic drug for a brand-name prescription drug[2] or to seek the prescribing physician's approval for such substitution.[3] Other sates prohibit any substitution without the prescribing physician's approval.[4]

The FDA's rules allow manufacturers to develop new versions of approved brand-name drugs, including different delivery routes. *Id.* ¶ 43. Because the FDA does not consider them the "same dosage form," however, such products are not pharmaceutical equivalents and cannot receive an "AB-rating." *Id.* ¶ 43. In this case, because they are not the same dosage form, a film product will not be an "AB-rated" to a tablet product, or vice versa. *Id.* ¶ 55.

When a risk or safety concern arises about a drug, the FDA can require the drug manufacturer (whether brand-name or generic) to submit and adhere to a Risk Exposure Mitigation Strategy ("REMS") that addresses the concern. 21 U.S.C. § 355-1(a). To maximize the safety of all drugs, any member of the public, including makers of competing drugs, can alert the FDA about a safety concern. 21 C.F.R. § 10.30 (2016). The FDA must review and act upon such a "citizen petition" within 150 days of the filing date, but must approve a new drug that meets the requirements for approval, even if the drug is the subject of a pending citizen petition. 21 U.S.C. § 355(q)(1)(A), (F).

[2] *See* Conn. Gen. Stat. § 20–619(b); Minn. Stat. § 151.21 Subd. 3.
[3] *See* N.J. Stat. Ann. § 24:6E-8; N.D. Cent. Code § 19–02.1–14.1(3); Tex. Occ. Code § 562.012; Wash. Rev. Code § 69.41.130.
[4] *See* Okla. Stat. tit. 59, § 353.13(D); S.C. Code Ann. § 39-24-20(3).

B. MonoSol's Alleged Conduct

MonoSol developed a novel film delivery method suitable for multiple medical uses. FAC ¶ 47. MonoSol marketed the new technology to potential business partners, including on a web site. *Id.* ¶ 48. In December 2006, MonoSol and RBH agreed to develop a film version of Suboxone—a drug that Reckitt was exclusively authorized by the FDA to market in a tablet form through October 8, 2009. *Id.* ¶¶ 37, 47. Suboxone film came on the market in 2010 after nearly four years of efforts to develop the drug and complete the rigorous regulatory approval process. *Id.* ¶¶ 37, 60. MonoSol manufactures the Suboxone film that Reckitt markets to doctors or patients. *See id.* ¶ 23, 25, 46. In return for licensing its patented film technology and applying its manufacturing know-how, MonoSol receives from Reckitt licensing fees and royalties linked to the quantity of Suboxone film sold. *Id.* ¶ 49. MonoSol optimized the production process to reduce production costs and enable competitive pricing below the brand-name tablet. *Id.* ¶ 85.

Under relevant laws and regulations, generic Suboxone tablets could have been introduced on the market as early as October 9, 2009, the day after Reckitt's exclusivity period ended. *See id.* ¶ 36. But no generic manufacturer had sought FDA approval in time. Manufacturers of generic Suboxone tablets filed ANDAs for their products in 2009. *Id.* ¶ 89. The ANDAs were still pending in late 2011. *Id.* ¶ 90. Furthermore, once the FDA required a REMS (*id.* ¶ 92), the ANDAs could not be approved before the generic manufacturers submitted their REMS, allegedly on May 6, 2012, at the earliest. *Id.* ¶ 97. In the end, the first generic Suboxone tablets did not go on the market until March 6, 2013, twelve days after the FDA approved the first two ANDAs for generic Suboxone tablets. *Id.* ¶¶ 114, 115.

C. Prior Ruling of this Court

In December of 2014, this Court ruled on a motion to dismiss a class action complaint against Reckitt arising out of the same events that Plaintiff States allege here. *See In re*

Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., 64 F. Supp. 3d 665 (E.D. Pa 2014) ("*In re Suboxone*"). Notably, the class action plaintiffs did not allege any violation of law by MonoSol or any conspiracy claims against Reckitt. In its ruling, this Court re-affirmed the holdings in a line of similar cases that "simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit." *Id*. at 682. The Court, therefore, refused to uphold the complaint merely on the theory that Reckitt introduced a new version of Suboxone solely to benefit from additional patent protection. The Court denied dismissal based on class plaintiffs' theory that Reckitt allegedly coerced consumers to substitute film for tablets by making allegedly misleading statements about the safety of tablets and announcing plans to withdraw the tablet form from the market, *id*. at 683-84, in which MonoSol had no role. *See infra* Section I.C.3.

LEGAL STANDARD

Fed. R. Civ. P. 12(b)(6) requires dismissal of claims whose supporting allegations are not "plausible" and fail to "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To determine the sufficiency of a complaint under *Twombly* and *Iqbal*, a court must take the following three steps: (1) the court must "tak[e] note of the elements a plaintiff must plead to state a claim;" (2) the court should identify the allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth;" and (3) "where there are well-pleaded factual allegations, a

court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 221 (3d Cir. 2011) (citations omitted). In addition to allegations in the complaint and reasonable inferences that the court may draw from them, the court must consider facts contained in documents that Plaintiffs quote, rely on or otherwise incorporate by reference, as well as matters of which the Court may take judicial notice. *Carpenter Tech. v. Allegheny Techs.*, 646 F. Supp. 2d 726, 735 (E.D. Pa. 2009) (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007)).[5]

Even though the court must accept a complaint's allegations as true, the court should give no weight to "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Iqbal*, 556 U.S. at 678; *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 258 (3d Cir. 2010) ("[M]erely saying so does not make it so for pleading-sufficiency purposes."). The court should also disregard pleadings that "make no sense, or that would render a claim incoherent, or that are contradicted either by statements in the complaint itself or by documents upon which its pleadings rely, or by facts of which the Court may take judicial notice." *In re Livent, Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 405-06 (S.D.N.Y. 2001).

ARGUMENT

Plaintiffs fail to state a claim against MonoSol under the Sherman Act or the various state statutes under which they sue. To state a claim for conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, a plaintiff must adequately allege (1) concerted action by the defendants; (2) that produced anticompetitive effects within the relevant product and geographic

[5] Fed. R. Evid. 201 (b)(2) permits a court to take judicial notice of facts that are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." *See Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) (court may rely on "undisputedly authentic" documents); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa 2003) (taking judicial notice of report published on FDA's website in deciding motion to dismiss).

markets; (3) that the concerted actions were illegal; and (4) that it was injured as a proximate result of the concerted action. *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 207 (3d Cir. 2005). A claim for conspiracy to monopolize in violation of Section 2 of the Sherman Act requires adequate allegations of (1) an agreement to monopolize; (2) an overt act in furtherance of the conspiracy; (3) a specific intent to monopolize; and (4) a causal connection between the conspiracy and the injury alleged. *Dentsply*, 602 F.3d at 253. Although the precise elements of Plaintiffs' state-law claims against MonoSol vary, *see infra* Section V, they all depend on participation by MonoSol in an illegal conspiracy that caused cognizable injury. Thus, failure to allege adequately that MonoSol participated in an illegal conspiracy or that its actions caused Plaintiffs' alleged injuries dooms all claims against MonoSol. Counts III and IV also fail for inadequately pleading the required elements relevant market and specific intent to monopolize.

I. All Counts Against MonoSol Fail Because Plaintiffs Do Not Adequately Allege that MonoSol Participated in an Unlawful Anti-Competitive Agreement

To allege an unlawful conspiracy under Section 1 or Section 2 of the Sherman Act, Plaintiffs must allege "facts plausibly suggesting 'a unity of purpose or a common design and understanding, or a meeting of the minds *in an unlawful agreement*.'" *Dentsply*, 602 F.3d at 253-254 (emphasis added) (quoting *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 771 (1984)). A plaintiff must also allege the "specific time, place or person[s]" involved in the alleged conspiracy," *Twombly*, 550 U.S. at 565, n. 10, and establish that the alleged conspirators "'had a conscious commitment to a common scheme *designed to achieve an unlawful objective*.'" *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 764 (1984) (emphasis added) (citation omitted).

Here, Plaintiffs allege that, in December 2006, MonoSol and RBH executed a contract that "initiated the joint venture to create and manufacture Suboxone film." FAC ¶ 12. Despite a

reference to "a series of agreements" between Reckitt and MonoSol (*id.* ¶ 25), Plaintiffs do not specify the nature, timing or persons involved in any other agreement between Reckitt and MonoSol. To the extent the FAC alleges joint actions by MonoSol and Reckitt, such as discussion of pricing for Suboxone film (*id.* ¶ 85), drafting portions of the NDA submissions to the FDA (*id.* ¶ 61), or attending meetings with the FDA (*id.* ¶ 53), none of these allegations permits a reasonable inference of a common scheme designed to achieve an *unlawful* objective.[6] On the contrary, all of these joint actions are consistent with MonoSol and Reckitt's roles as business partners whose core economic interests are merely aligned to develop and profit from a new product. The FAC also lacks factual support to infer that MonoSol's own actions foreclosed competitors or injured competition in the alleged relevant market.

A. MonoSol and Reckitt Cannot Conspire as a Matter of Law

Plaintiffs' contention that the "joint venture" of RBH and MonoSol constituted an illegal conspiracy is factually and legally insufficient. In *Copperweld*, the Supreme Court held that two or more legally distinct entities cannot conspire among themselves if they "pursue . . . the common interests of the whole," and so their conglomeration must be treated as a single entity rather than as a conspiracy. 467 U.S. at 770-71 (holding no conspiracy absent "a sudden joining of two independent sources of economic power previously pursing separate interests"). In *American Needle*, the Supreme Court emphasized that "substance, not form, should determine whether a[n] . . . entity is capable of conspiring under § 1" and reiterated that single entity status depends upon the degree of alignment of economic interests. *Am. Needle, Inc. v. Nat'l Football League*, 560 U.S. 183, 184-188, 195-196 (2010); *see also Carpenter Tech. Corp.*, 646 F. Supp.

[6] To the extent the allegations in paragraph 45 purport to describe the alleged conspiracy between Reckitt and MonoSol, rather than an alleged unilateral plan by Reckitt to address impending competition by generic manufacturers, neither of the two "steps" in the alleged plan represents an unlawful objective. *See Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 151-52 (D.D.C. 2008) (reasoning that "enjoying the benefits of patent protection" is not unlawful and neither is merely encouraging product switching).

2d at 734 (holding *Copperweld* doctrine "equally applicable to Section 2 conspiracy to monopolize claims" and dismissing complaint on *Copperweld* grounds).

Courts have applied the single-entity doctrine of *Copperweld* to a wide range of corporate relationships whenever the entities "were, in substance, one economic unit." *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1133 (3d Cir. 1995); *see also Eichorn v. AT&T Corp.*, 248 F.3d 131, 138-139 (3d Cir. 2001); *Fresh Made, Inc. v. Lifeway Foods, Inc.*, No. Civ. A. 01-4254, 2002 WL 31246922, at *7 (E.D. Pa. Aug. 9, 2002). For instance, the Supreme Court applied *Copperweld* to participants of a joint venture that had "agreed to pool their resources and agreed to share the risks of and profits from [the joint venture's] activities." *Texaco, Inc. v. Dagher*, 547 U.S. 1, 4 (2006); *see also Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 834-35 (3d Cir. 2010) ("Courts have applied [*Copperweld's*] single-entity concept to joint ventures of separately owned entities."). Courts have also held that patent holders and their exclusive licensees are incapable of conspiring. *See Sheet Metal Duct, Inc. v. Lindab, Inc.*, Civil Action No. 99-6299, 2000 WL 987865, at *6 (E.D. Pa. July 18, 2000) (where "alleged illegal behavior is purely derivative of the legal patent monopoly and legal exclusive distributorship, . . . there can be no claim against [the exclusive licensee] under Section 1 resulting from this agreement"); *Shionogi Pharma., Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 2174499, at *5 (D. Del. May 26, 2011); *Levi Case Co. v. ATS Prods., Inc.*, 788 F. Supp. 428, 432 (N.D. Cal. 1992) (patent holder and exclusive licensee do not have "independent sources of economic power" and are not independent actors in marketplace).

Courts have also held that a company and its agents were incapable of conspiring. For example, in *Siegel*, the Third Circuit held that a corporate principal, a freight transportation company, could not conspire with its agents that did not compete with the principal and whose

only function was to make arrangements for the transport of the principal's freight. 54 F.3d at 1135. The Third Circuit concluded that, because the agents received a commission from the principal based on the loads they arranged for the company to transport, the parties' economic interests were entirely congruent and, thus, they represented a single enterprise. *See id.*; *see also Peerless Heater Co. v. Mestek, Inc.*, No. CIV. A. 98-CV-6532, 2000 WL 637082, at *6 (E.D. Pa. May 11, 2000) (rejecting conspiracy among Mestek and its sales representatives receiving commissions from Peerless, because their interests were aligned).

Here, Plaintiffs' allegations repeatedly make plain that MonoSol and Reckitt share economic interests that are aligned by their legitimate development and manufacturing "joint venture" (FAC ¶ 12), making an illegal conspiracy impossible under *Copperweld* and its progeny. Like the joint venture partners in *Dagher*, MonoSol and Reckitt are alleged to have pooled resources and shared risks: The FAC alleges that MonoSol and Reckitt formed a joint venture to create Suboxone film, that MonoSol supplied its sublingual film patented technology to the joint effort (*see id.* ¶¶ 12, 51), that MonoSol and Reckitt developed Suboxone film "in partnership" (*id.* ¶ 47), sharing four years of regulatory uncertainty until the FDA permitted it to be marketed (*id.* ¶¶ 37, 60), as well as the subsequent risks of limited profits in the face of competition from alternative treatments and generic tablets. *See, e.g., id.* ¶ 55.

Like the patent licensors and licensees in *Shionogi Pharma* and *Levi Case*, MonoSol and Reckitt are alleged to have licensed each other exclusively; and MonoSol receives royalty and license payments directly linked to the sales of their joint product, *id.* ¶ 85. The FAC concedes that the royalty payments incentivized MonoSol to pursue the same economic goal shared by Reckitt, namely more sales of Suboxone film. *Id.*

Like the transportation agents in *Siegel* and the sales representatives in *Peerless*, who

supplied services for compensation linked to sales, MonoSol is alleged to supply technology and manufacturing services to Reckitt in return for royalty and patent license fees. *Id.* ¶¶ 47, 85. And as in *Siegel* and *Peerless*, MonoSol and Reckitt are nowhere alleged to compete with each other in any market whatsoever.

In sum, the FAC alleges that MonoSol is a supplier of technology and manufacturing services to Reckitt. There is no allegation that at any time—whether before or since the joint development of Suboxone film—MonoSol and Reckitt ever competed against each other in the alleged relevant market. Plaintiffs do not and cannot offer any factual basis to infer that MonoSol and Reckitt are separate actors in the alleged relevant market as required by *Copperweld* and its progeny for an illegal conspiracy to exist. Failure to properly allege a conspiracy is fatal to all of Plaintiffs' Sherman Act claims against MonoSol. *See, e.g.*, *Dentsply, Inc.*, 602 F.3d at 254 (viability of conspiracy claims under Section 1 and Section 2 of the Sherman Act arising from same conduct turns on sufficiency of allegations of conspiracy or concerted action); *Englert v. City of McKeesport*, 872 F.2d 1144, 1150 (3d Cir.1989); *Fragale & Sons Beverage Co. v. Dill*, 760 F.2d 469, 473–74 (3d Cir. 1985). Because illegal conspiracy is also at the center of all of Plaintiffs' state-law claims, *see infra* Section V, the failure to properly allege conspiracy dooms all of those claims, as well.

B. Agreeing to Develop and Introduce a New Product is Pro-Competitive

Assuming arguendo that the Court finds MonoSol and Reckitt legally able to conspire, Plaintiffs' conspiracy claims still fail because the FAC does not allege facts demonstrating that MonoSol's participation in the joint development and manufacturing of Suboxone film injured competition. As this Court noted in the class action litigation, introducing a new product ordinarily is pro-competitive and can only be deemed anticompetitive when, among other requirements, the product introduction is accompanied by additional conduct that is coercive and

forecloses the market from competition. 64 F. Supp. 3d at 683-84; *see also Apotex*, 383 F. Supp. 2d at 686, 696-98 (E.D. Pa. 2004) (holding that introducing a new product by definition increases competition in relevant market). The Third Circuit recently reiterated this principle when it affirmed this Court's ruling that even a series of four "product hops" similar to the one alleged here was not anticompetitive unless competitors were foreclosed from the market. *See Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 438 (3d Cir. 2016).

It is not sufficient to allege that a new product is inferior to existing competing products. *See, e.g., Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286-87 (2d Cir. 1979) ("If a monopolist's products gain acceptance in the market, therefore, it is of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion."). Thus, Plaintiffs' allegations that film was inferior to or less safe than tablet (FAC ¶¶ 64-67) are no basis to convert into anticompetitive acts MonoSol's and Reckitt's ordinarily pro-competitive joint development and introduction of Suboxone film.

Nor is it sufficient to allege that the seller of a new product sought to attract customers by encouraging a switch away from existing products. *See, e.g., AstraZeneca AB v. Mylan Labs. Inc.*, Nos. 00 Civ. 6749, 03 Civ. 6057, 2010 WL 2079722, at *2 (S.D.N.Y. May 19, 2010) (dismissing claims that innovator violated Sherman Act Sections 1 and 2 where plaintiff alleged efforts to "convert sales of" Prilosec to Nexium and similar drugs, "thereby replacing revenue that would otherwise have gone to suppliers of generic omeprazole products"). Thus, Plaintiffs' allegations of MonoSol and Reckitt's desire "to thwart generic entry" (FAC ¶ 50), to "maintain Reckitt's market share" (*id.*), to "avoid competition from generic entrants" (*id.* ¶ 63), or to protect from "generic incursion" (*id.* ¶ 69), without more, suggest only a pro-competitive response to expected competition by introducing a differentiated version of the Suboxone

treatment. The antitrust laws do not require anyone to slow down innovation, delay introduction of new products, continue selling unprofitable products, or do anything else to enhance the chances of competitors to succeed. *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004) ("[T]here is no duty to aid competitors.").

C. No Adequately Pled Facts Support the Inference that MonoSol Engaged in Exclusionary Conduct

Without pleading that MonoSol participated in exclusionary conduct, Plaintiffs cannot plausibly allege that MonoSol's mere enablement of product switching by supplying pharmaceutical film technology was anti-competitive. *In re Suboxone*, 64 F. Supp. 3d at 668; *see also Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C.2008) (dismissing complaint where defendant brand-name drug manufacturer pursued product switching strategy but did not engage in exclusionary conduct).

Conduct is exclusionary when it involves "competition on some basis other than the merits" or "unfairly tends to destroy competition itself." *Mylan Pharms.*, 838 F.3d at 438 (3d Cir. 2016) (citations omitted). Exclusionary conduct has also been defined as "conduct without a legitimate business purpose that makes sense only because it eliminates competition." *Behrend v. Comcast Corp.*, Civil Action No. 03-6604, 2012 WL 1231794, at *19 (E.D. Pa. Apr. 12, 2012) (citation omitted). However, intent to harm a competitor does not make actions exclusionary if the actions do not tend to reduce competition. *See, e.g., Olympia Equipment Leasing Co. v. Western Union Tel. Co.*, 797 F.2d 370, 379 (7th Cir. 1986) ("[I]f conduct is not objectively anticompetitive the fact that it was motivated by hostility to competitors . . . is irrelevant[.]"); *Bloch v. Smithkline Beckman Corp.*, Civil Action No. 82-510, 1988 U.S. Dist. LEXIS 12397, at *17 (E.D. Pa. Nov. 1, 1988).

Here, Plaintiffs have not alleged any facts demonstrating that any of MonoSol's actions

restricted consumer choice or foreclosed competition. Plaintiffs have not alleged that MonoSol was involved in any way in any alleged misleading communications about the safety of the Suboxone tablet or in any alleged refusal to cooperate with the generic manufacturers in their development of the required REMS. FAC ¶¶ 73-75, 94-95. Plaintiffs' allegations against MonoSol center on (1) MonoSol's efforts to market its film technology as a differentiator for products going off patent, (2) its efforts to reduce costs and accelerate production of Suboxone film, (3) stating the obvious truth that film sales would rise if there were no tablets on the market, and (4) unspecified discussions with Reckitt about a potential citizens petition. None of these describes actions that reduce consumer choice, foreclose competitors, or make no economic sense absent exclusionary effects.

1. Convincing Reckitt to reformulate its Suboxone tablet with MonoSol's sublingual film delivery technology is not exclusionary conduct.

Plaintiffs' allegations that MonoSol encouraged Reckitt to introduce a reformulated version of its Suboxone treatment and represented to Reckitt that such a strategy would be profitable (*id.* ¶¶ 47-48), cannot support an inference of exclusionary conduct. Stripped of innuendo, MonoSol's alleged web site statements amount to nothing more than a valid patent holder's pitch to potential licensees and business partners explaining how they might profit from adopting its innovation. None of the alleged statements refers to forcing patients to switch to film or preventing generic versions from entering the market. Nor have Plaintiffs alleged that any of the statements on MonoSol's web site were false or misleading or even that they had any direct effect on competition in the alleged relevant market.

Merely bringing a new product to market can only increase consumer choice rather than restrict it. Moreover, the FAC's allegations of projected profits show that the suggested product-switching strategy made perfect economic sense. The product-switching that MonoSol allegedly

suggested was not by itself anticompetitive or prohibited by law. *See In re Suboxone*, 64 F. Supp. 3d at 668; *see also* FAC ¶ 43 ("FDA regulations allow branded manufacturers to seek FDA approval to modify the dosage form and strength of their existing products."); *See infra* Section III.B.

2. Pricing a new product below competing products to attract customers is competition on the merits, not exclusionary conduct.

Plaintiffs allege that MonoSol optimized the cost of producing Suboxone film to enable the pricing of Suboxone film at a lower price than the Suboxone tablet, which in turn would "encourage the product switch." FAC ¶ 85. Only predatory pricing—which by definition is pricing by a monopolist below a relevant measure of cost with the reasonable prospect of later raising and maintaining prices high enough to recoup losses—can be anticompetitive. *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 339 (1990) ("[I]n the context of pricing practices, only predatory pricing has the requisite anticompetitive effect."); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588–589 (1986) ("[T]he [predator] must have a reasonable expectation of recovering, in the form of later monopoly profits, more than the losses suffered."). There are and can be no allegations of predatory pricing here, as Plaintiffs allege that the sales of Suboxone film generated profits. *Id.* ¶ 85.[7]

3. *Saying* that sales of Suboxone film would increase if Reckitt stopped selling the tablet version is not exclusionary conduct.

The allegation that MonoSol "made the initial suggestion" about Reckitt withdrawing the Suboxone tablets from the market (FAC ¶ 71) fails to implicate MonoSol in any allegedly wrongful conduct. Although Paragraph 71 is grammatically incoherent and fails to provide

[7] Moreover, Plaintiffs do not specify what pricing was the subject of the alleged "numerous conversations" between MonoSol and Reckitt. FAC ¶ 85. Plaintiffs do not allege that MonoSol was involved in decisions about the pricing of Suboxone film to patients. Because MonoSol manufactures the film for Indivior, Inc. the price which MonoSol would receive from Indivior, Inc. for the film is a proper subject of such conversations between contracting parties.

adequate detail about who, when, and where the "suggestion" was made, it suffices to note that it clearly fails to specify any time-frame. When the alleged suggestion was made and when the withdrawal was suggested to occur are both critical, as there could be no harm from withdrawing the brand-name tablet, much less "suggest[ing]" to do so, once generic versions were available on the market. There is also no allegation that MonoSol had any control over Reckitt's decisions about the marketing, pricing, or discontinuance of its tablet. Suggesting or discussing actions that *might* harm rivals or result in fewer available products is not the same as *actually* harming rivals or consumers. Moreover, Plaintiffs' allegations that Reckitt in fact withdrew the tablet only after generic versions entered the market (*id.* ¶¶ 88, 115) contradict any inference of harm to competition or market participants and any inference of an agreement between MonoSol and Reckitt to withdraw the tablet before generic entry or at any time. At all times when film was on the market, consumers have had and continue to have the option to purchase a tablet—either brand-name or generic—in addition to other treatments for opioid addiction.

4. Participating in meetings about *a possible* citizen petition is protected First Amendment activity and is not exclusionary conduct.

The First Amendment protects any alleged meetings between MonoSol and Reckitt regarding a possible citizen petition. *See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136–38, 144–45 (1961); *Mine Workers v. Pennington*, 381 U.S. 657, 669–72 (1965); *see also Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007) ("In activities that enjoy First Amendment protection, such as lobbying, firms may enjoy broad immunity from antitrust liability for concerted efforts to influence political action in restraint of trade, even when such efforts employ unethical or deceptive methods."). Allegations that the citizen petition was a sham, and therefore not immune, are inapposite, because MonoSol is merely alleged to have discussed the *possibility* of a petition. Indeed, Plaintiffs do not even

allege that MonoSol ever knew the content of Reckitt's petition until it eventually was filed.[8]

Even if the alleged meetings about the petition were not protected First Amendment activity, which they are, Plaintiffs' allegations of participation in meetings are insufficient to allege exclusionary conduct. The sole alleged purpose of these meetings was to "*explore* what [citizen petition] *opportunities* may exist" regarding Suboxone tablets. FAC ¶ 112 (emphasis added). Plaintiffs do not allege that MonoSol actually joined in submitting or writing the petition Reckitt filed. In fact, it was signed and submitted by Reckitt only.[9] There is no allegation that could support an inference that MonoSol's participation in these alleged exploratory meetings influenced in any way the timing of the entry of generic tablets.

II. Counts III and IV Fail Also Because Plaintiffs Do Not Adequately Allege that MonoSol's Conduct Proximately Caused their Injuries

A fundamental requirement of antitrust causation is that the alleged anticompetitive conduct actually caused the claimed injury. 15 U.S.C. § 15(a); *see, e.g., Stelwagon Mfg. Co. v. Tarmac Roofing Sys., Inc.*, 63 F.3d 1267, 1273 (3d Cir. 1995) (requiring a "causal connection" between alleged antitrust violation and plaintiff's alleged injury); *City of Pittsburgh v. W. Penn. Power Co.*, 147 F.3d 256, 265 (3rd Cir. 1998) (finding no antitrust injury because "any injury suffered by the City did not flow from the defendants' conduct, but, rather, from the realities of the regulated environment in which all three were actors"). A claim must be dismissed when an independent cause breaks the causal connection between the alleged antitrust violation and the plaintiff's alleged harm. *See, e.g., City of Pittsburg*, 147 F.3d at 265.

Plaintiffs claim that their citizens sustained losses due to the delayed entry of allegedly

[8] In addition, Tennessee has explicitly based its Consumer Protection Act claim on MonoSol's alleged "actions or omissions during the FDA approval process…" FAC ¶ 278. Under *Noerr-Pennington*, the First Amendment precludes Tennessee's—and any other state's—claims based on this conduct.

[9] *See* Exhibit 1 at 48 (Citizen Petition filed by Tim Baxter, *Medical Director, Reckitt Benckiser Pharmaceuticals, Inc.*, Sept. 25, 2012, https://www.regulations.gov/document?D=FDA-2012-P-1028-0001). The Court may take judicial notice of this document. *See infra* note 5. As the Plaintiffs know well, MonoSol did submit a *different* citizen petition wholly unrelated to this case.

cheaper generic Suboxone tablet. FAC ¶ 119. Plaintiffs also claim that the losses continued even after generic tablets were available on the market, because patients and doctors chose film over tablet forms which allegedly precluded automatic substitution of generic tablets for brand-name film under some state laws.[10] In both cases, supervening causes broke the chain of causation.

First, even assuming that MonoSol had any role in preparing or submitting Reckitt's citizen petition, any alleged delay in the generic ANDAs' approval while the FDA was reviewing the petition resulted from an "arbitrary act[] of government bureaucracy" not to grant the ANDAs earlier. *Exxon Corp. v. Amoco Oil Co.*, 875 F.2d 1085, 1089 (4th Cir. 1989) (reversing denial of judgment as a matter of law because of superseding government act); *Midland Export, Ltd. v. Elkem Holding, Inc.*, 947 F. Supp. 163, 166 (E.D. Pa. 1996) (finding lack of antitrust standing because ITC's "independent determination" was "the direct cause of the harm alleged here"). The FDA is statutorily prohibited from delaying any ANDA approval "either before or during consideration" of a citizen petition. 21 U.S.C. § 355(q)(1)(A).[11] Thus, the filing of a citizen petition could not plausibly have delayed generic entry here absent allegations that MonoSol influenced how long the FDA reviewed the ANDAs and Reckitt's citizen petition or allegations that the FDA exceeded the 150 day statutory period for such review. FAC ¶¶ 102, 108; 21 U.S.C. § 355-1(q). More importantly, however, throughout the time that any ANDA's approval was allegedly delayed, Suboxone film was a cheaper alternative to the brand-name tablet; and the film's availability could have only benefited Plaintiffs.

[10] Any injury allegedly stemming from the avoidance of automatic substitution laws could only apply to those states whose laws (a) *required* pharmacists to substitute a generic product for a brand-name one without the prescriber's approval *and* (b) at the same time *prohibited* pharmacists from substituting a non-AB-rated generic for the brand-name drug or from seeking prescriber's approval to do so. Otherwise, decisions by pharmacists and prescribers are intervening causes.

[11] Furthermore, the FDA has issued a formal "Guidance to Industry" that the FDA will delay responses to citizen petitions until it issues its decision about related ANDAs. *See* Memorandum in Support of Indivior, Inc.'s Motion to Dismiss, section V.C, which MonoSol incorporates herein by reference.

Second, prescribing physicians determined whether to prescribe the film form or the tablet (generic or brand-name) of Suboxone to each of their patients and thus whether generic substitution laws would operate on the prescription. *See, e.g.*, *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 851 (10th Cir. 2003) ("[P]hysicians based upon knowledge of their own patients, bear the final responsibility for the decision to prescribe medications . . . ."); *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 382 (D.N.J. 2004) ("It is for the prescribing physician to use his own independent medical judgment, taking into account the data supplied to him from the drug manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug.") (citation omitted). Plaintiffs cannot complain that fewer generics were sold because of the presence of film in the marketplace. It is well settled that there can be no injury under the antitrust laws based on having to compete more, rather than less. *Brunswick Corp. v. Pueblo Bowl-o-Mat, Inc.*, 429 U.S. 477, 489-90 (1977) (injury caused when a rival is forced to face more competition instead of less is not injury of the type that the antitrust laws protect); *Sanjuan v. Am. Bd. of Psych. & Neurology, Inc.*, 40 F.3d 247, 251 (7th Cir. 1994) ("The claim that a practice reduces (particular) producers' incomes has nothing to do with the antitrust laws . . . .").

Finally, the conclusory allegation that "[b]ut for Reckitt and MonoSol's illegal conduct, generic competition to Suboxone Tablets would have been available when orphan exclusivity expired in October, 2009" (FAC ¶ 119) is contradicted by other factual allegations and the publicly available record. Plaintiffs do not allege any facts showing that the generic manufacturers filed their ANDAs early enough for the FDA to approve generic Suboxone tablets by the time Reckitt's exclusivity expired on October 8, 2009. To the contrary, generic manufacturers could not market their tablets before the FDA approved their ANDAs, and the

FDA could not approve the ANDAs without REMS. *Id.* ¶¶ 22, 28, 91, 95. The FAC alleges that the generic manufacturers would have submitted REMS by May 6, 2012, if Reckitt had assisted in preparing the REMS. *Id.* ¶ 97. Thus, even if Reckitt had helped its generic competitors with their REMS (which antitrust law does not require) and even if the FDA had approved the ANDAs soon after receiving the generic manufacturers' REMS (which Plaintiffs do not allege), generic tablets would not have been on the market in October 2009. Any loss that Plaintiffs allegedly sustained due to a lack of generic alternative to the tablet cannot be attributed to any conduct by MonoSol or Reckitt, because the generics were not ready for market when orphan exclusivity expired in October 2009. And, again, while the ANDAs were pending, the availability of film as a cheaper alternative to the tablet actually benefited Plaintiffs rather than hurt them.

III. Counts IV Fails Also Because Plaintiffs' Allegations of Other Key Elements are Insufficient

Plaintiffs fail to state a claim because they have not adequately pled a relevant market and specific intent by MonoSol to monopolize the alleged relevant market. Failure to properly allege any of these elements provides a separate and independent ground for dismissal of Plaintiffs' conspiracy to monopolize claims. *See, e.g., Dentsply*, 602 F.3d at 253 (stating the elements of a Section 2 claim).[12]

A. Plaintiffs' Allegations of Relevant Product Market are Implausible

A relevant market in antitrust cases must capture all and only products that are reasonably substitutable for each other. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436

[12] Plaintiffs also fail to properly allege acts that MonoSol took in furtherance of a Section 2 conspiracy. They conclusorily allege that all of MonoSol's actions were "in furtherance of, the illegal monopolization, attempted monopolization and unfair and deceptive practices alleged herein." FAC ¶ 16. But there are no claims against MonoSol for monopolization or attempted monopolization. Unlike for Reckitt, *see id.* ¶ 56, Plaintiffs do not even try to identify any actions that MonoSol allegedly took in furtherance of the alleged Section 2 conspiracy.

(3d Cir. 1997) ("Where the plaintiff . . . alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products even when all factual inferences are granted in plaintiff's favor, the relevant market is legally insufficient and a motion to dismiss may be granted.") The alleged relevant market comprised of Suboxone tablet, Suboxone film and all of their AB-rated generic alternatives fails to do that for at least two reasons. First, the market allegations are inherently self-contradictory about what is reasonably substitutable. On the one hand, non-AB-rated generic Suboxone tablets are excluded from the market because allegedly a treatment that is not pharmaceutically equivalent to the brand-name Suboxone tablet is not a reasonable substitute for it. FAC ¶ 20. On the other hand, however, the alleged market includes Suboxone film, which is not pharmaceutically equivalent to Suboxone tablet. *Id.* ¶ 55. Plaintiffs cannot have it both ways: either pharmaceutical equivalence is required for reasonable substitutability, in which case there cannot be a single market combining film and tablet forms, or it is not required, in which case the relevant market cannot automatically exclude other addiction treatments that are not pharmaceutically equivalent.

Second, the alleged relevant market improperly excludes Methadone on the basis of the mode of its administration and Subutex on the basis of a difference in active ingredients. The operative question should be not whether the drugs are administered under the same conditions or have the same active ingredients, but whether the drugs produce the desired therapeutic result in treating the conditions for which they are prescribed. *Allen–Myland, Inc. v. Int'l Bus. Mach. Corp.*, 33 F.3d 194, 206 (3d Cir. 1994) ("Interchangeability implies that one product is roughly equivalent to another *for the use to which it is put*; while there may be some degree of preference for the one over the other, either would work effectively." (emphasis added)); *Mylan Pharms., Inc. v. Warner Chilcott Pub. Co.*, Civ. No. 12-3824, 2015 WL 1736957, at *8 (E.D. Pa. Apr. 16,

2015) (rejecting relevant market that included only Doryx and excluded other oral tetracycline acne treatments on the basis of Doryx's specific side effects profile and tolerability by certain patients), *aff'd*, 838 F.3d 421 (3d Cir. 2016). Failing to include Methadone and Subutex in the alleged relevant market is fatal to Plaintiffs' claims. *Queen City Pizza*, 124 F.3d at 436.

B. Plaintiffs Do Not Adequately Plead that MonoSol Acted with Specific Intent to Maintain or Help Reckitt Maintain an Unlawful Monopoly in the Alleged Relevant Market

Plaintiffs' allegations that the introduction of Suboxone film was "intended to thwart generic entry" (FAC ¶ 50), to "maintain Reckitt's market share" (*id.*), to "avoid competition from generic entrants" (¶ 63), to protect from "generic incursion" (¶ 69), or to "prevent generic competition" (¶ 154) are conclusory and unsupported by factual allegations. The only factual allegations in the FAC that could support these conclusions are that MonoSol and Reckitt introduced a new product to compete with generic versions of the Suboxone tablet. These allegations do not adequately plead specific intent to monopolize. *See Dentsply*, 602 F.3d at 257 (affirming dismissal for failure to allege specific intent to monopolize where plaintiffs alleged that defendants "have acted with the specific intent to unlawfully maintain a monopoly" and "the intended effect . . . has been the elimination of any and all competition") (citation omitted).

Similarly, Plaintiffs cannot sufficiently plead specific intent to monopolize by alleging that MonoSol marketed pharmaceutical film as a possible means for drug companies to maintain their customer base in the face of generic competition (FAC ¶¶ 48, 151). *See Gordon*, 423 F.3d at 214-215 (plaintiff must allege more than the defendant's intent to protect or expand its market position relative to its competitors). At most, the alleged quotations from MonoSol's Internet website appropriately highlight how introducing a new delivery mechanism for existing drugs could help brand-name drug manufacturers differentiate their products from competing generic versions. *See, e.g., Allied Orthopedic Appliances, Inc. v. Tyco Health Care Group LP*, 592 F.3d

991, 1000 (9th Cir. 2010) ("[P]roduct improvement by itself does not violate Section 2, even if it is performed by a monopolist and harms competitors as a result.")

Finally, Plaintiffs cannot rely on any inferences of specific intent based on alleged exclusionary conduct because Plaintiffs have failed to adequately plead that MonoSol engaged in any such unlawful conduct. *Cf., e.g., Advo, Inc. v. Phila. Newspapers, Inc.*, 51 F.3d 1191, 1199 (3d Cir.1995) (permitting specific intent to be inferred from defendant's unlawful conduct).

IV. All Counts Against MonoSol Fail Because Plaintiffs' Sherman Act and State Law Claims Against MonoSol are Time Barred

The applicable limitations period for the alleged Sherman Act and federal causes of action is four years.[13] Plaintiffs filed their first complaint on September 22, 2016. The last alleged action by MonoSol—the citizen petition meetings—took place "as early as 2011." FAC ¶ 112. Therefore, Plaintiffs cannot recover for injuries arising out of actions that MonoSol allegedly undertook prior to September 22, 2012. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971) ("a cause of action accrues and the statute begins to run when a defendant commits an act that injures a plaintiff's business").

[13] 15 U.S.C. § 15b (Sherman Act); D.C. Code § 28-4511 (2016); Ala. Code § 8-19-14 (1981); Alaska Stat. § 45.50.588 (1980); Alaska Stat. § 45.50.531(f) (1970); Cal. Bus. & Prof. Code § 16750.1 (1977); Cal. Bus & Prof. Code § 17208 (1977); Colo. Rev. Stat. § 6-4-118 (1992); Conn. Gen. Stat. § 35-40 (1971); Conn. Gen. Stat. § 52-577 (1971); Del. Code Ann. tit. 6, § 2101 (2016); Fla. Stat. § 542.26 (2016); Ga. Code Ann. § 10-1-401(a) (2015); Haw. Rev. Stat § 480-24 (2016); Idaho Code Ann. § 48-115 (2000); 740 Ill. Comp. Stat. 10/7 (2009); Iowa Code § 553.16 (2016); Ky. Rev. Stat. Ann. 367.220 (1974); Md. Code Ann., Com. Law. § 11-209(d) (2005); Mich. Comp. Laws Ann. § 445.781 (2016); Minn. Stat. § 325D.64 (1971); Miss. Code Ann. § 15-1-49 (1972); Mo. Rev. Stat. § 416.131 (1974); Neb. Rev. Stat. § 59-1612 (1974); N.H. Rev. Stat. Ann. § 356.12 (2016); N.M. Stat. Ann. § 57-1-12 (1978); Or. Rev. Stat. § 646.800(1) (2016); R.I. Gen. Laws § 6-36-23 (2016); S.C. Code Ann. § 39-5-150 (1971); Tenn. Code Ann. § 28-3-105 (2016); Utah Code Ann. § 76-10-3117 (2016); Va. Code Ann. § 59.1-9.14 (2016); Wash. Rev. Code Ann. § 19.86.120 (2016); W. Va. Code § 47-18-11 (1978); *In re Lamictal Indirect Purchaser & Antitrust Consumer Litig.*, Civ. No. 12-5120 (WHW)(CLW), 2016 U.S. Dist. LEXIS 65382, at *4–5 (D.N.J. May 18, 2016); *Richardson v. Bank of Am.*, N.A., 643 S.E.2d 410, 422 (N.C. Ct. App. 2007); *Wilson v. Johnson*, Case No. CIV-05-0921-F, 2006 U.S. Dist. LEXIS 36759, at *10 (W.D. Okla. Jun. 5, 2006); *In re Linerboard Antitrust Litig.*, 223 F.R.D. 335, 342 (E.D. Pa. 2004); *Compagnie de Reassurance d'lle de Fr. v. New England Reinsurance Corp.*, 944 F. Supp. 986, 991 (D. Mass. 1996).

V. Count V Fails to State Claims Under the States' Antitrust, Consumer Protection and Unfair Trade Practices Statutes

As explained in Section IV of Defendant RBH's Memorandum of Law in Support of its Motion to Dismiss, which MonoSol joins and incorporates herein by reference, Plaintiffs' state claims are deficient for a number of reasons, including, most importantly, because the state antitrust, consumer protection and unfair trade practice statutes or the case law interpreting them indicate that they should be construed in harmony with federal antitrust law.

CONCLUSION

For the reasons stated above, the Court should dismiss the claims against MonoSol in their entirety.

Dated: December 12, 2016

Respectfully submitted,

s/Thomas M. Barba
Thomas M. Barba
James F. Hibey
Kenneth P. Ewing
Andrew J. Lee
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, N.W.
Washington, D.C. 20036
Tel.: (202) 429-3000
Fax: (202) 429-3902
Attorneys for MonoSol Rx, LLC